5.0 510(K) SUMMARY

APR 29 2010

5.1 Summary information

5.1.1 Submitter's name and address

Howard Smith, Engineering Director
CamNtech, UK, Ltd.
Upper Pendrill Court
Ermine Street North
Papworth Everard
Cambridge, United Kingdom CB233UY
Tel: 011-44-1480-831223
Fax: 011-44-1480-831733

Date summary was prepared: 01/25/2010

5.1.2 Name of device

Trade Name:	*Actiwave™*
Common Name:	Digital Ambulatory Monitor
Classification Name:	Electrocardiograph, Ambulatory (Without Analysis)
Product Regulation:	21 CFR 870.2800
Product Code:	MWJ

5.1.3 Identification of predicate device

SEER Light Compact Digital Holter Recorder, 510(k) Number : K021470

5.2 Device description

5.2.1.1 Functions of the device

Actiwave is a compact, ambulatory, battery-operated physiological signal recorder. *Actiwave* is commonly known as an Ambulatory Electrocardiograph. Because of its small size and battery operation, *Actiwave* may be used in a clinical or non-clinical setting to record physiological signal waveforms while the patient is unattended. The device obtains its signal from the skin surface through the use of standard gel-type signal electrodes. *Actiwave* may be worn during daily activities and is fully ambulatory due to its small size and its battery-operated power source. Recorded data may be transferred later to a personal computer for storage and archiving. *Actiwave* does not provide any data viewing or data analysis functions.

5.2.1.2 Basic scientific concepts

The *Actiwave* device acquires and logs digital data whose values represent the amplitude-varying physiological waveform signal voltages at progressive time intervals. The scientific concepts and technologies that are used to sense the signals are summarized in Table 5.1.

TABLE 5.1: BASIC TECHNOLOGIES USED FOR PHYSIOLOGICAL SIGNAL RECORDING IN *ACTIWAVE* RECORDERS

Physiological Parameter	Recorder Used	Technology	Value Obtained
Physiological waveform	*Actiwave1-, 2-, and 4-channel recorders and Actiwave Cardio*	Amplifier senses and amplifies voltage signal.	Digital value corresponding to instantaneous signal voltage.
Activity	*Actiwave Cardio*	Signal from accelerometer amplifier is digitized and recorded.	Digital value corresponding to Activity Counts or acceleration.

5.2.1.3 Physical characteristics of Recorder

Pertinent physical characteristics of the *Actiwave Recorder* are shown in Table 5.2.

TABLE 5.2: PHYSICAL CHARACTERISTICS OF *ACTIWAVE* RECORDER

Parameter	Value	Condition/Note
Size	Actiwave 1-channel: 19x27x9 mm Actiwave 2-channel: 25x27x9 mm Actiwave 4-channel: 37x27x9 mm Actiwave Cardio: 32diam x 10 mm	Outer dimensions
Weight	1-channel: 5 gm 2-channel: 6 gm 4-channel: 9 gm Cardio: 10 gm	With no electrodes attached
Case material	Polycarbonate/ABS	
Attachment type	Stainless steel snap connector or standard no-touch connectors	
Battery type	3.0 volt lithium rechargeable	Not user replaceable
Indicators	None	

5.3 Statement of the intended use of the device

The Actiwave Recorder is an ambulatory, body-worn, dermally-affixed, physiological signal and activity recorder having 1, 2, or 4 channels of physiological waveform storage. Actiwave is indicated for use in recording physiological waveforms and activity as part of a physiological recording system. The subject is not restricted to a medical environment. The subject may participate in normal activities while the Actiwave recorder is in place. Actiwave is a multi-use recorder. Actiwave may be used wherever quantifiable measurement of human physiological signal waveforms and/or activity are needed. Actiwave may be used in a clinical setting or in basic scientific research under the supervision of a trained clinician.

5.4 Technological characteristics of the device compared to predicate device

Actiwave and the *SEER Light Compact Digital Holter Recorder* (FDA 510(k) Number: K021470) are each physiological recording systems based upon the concept of an ambulatory, unattended physiological recorder that logs physiological data to the recorder. Each of these devices is a solid-state recorder with electronic amplifiers, data collection means, and with the ability to store data until it is transferred to a personal computer. *Actiwave* and the *SEER Light Compact Digital Holter Recorder* are of similar mechanical materials, construction, size, and human interface characteristics. *Actiwave* and the *SEER Light Compact Digital Holter Recorder* are of similar electronic design and their operational characteristics are functionally equivalent.

5.5 Assessment of non-clinical performance data and safety testing

The performance of the *Actiwave Recorder* has been tested in accordance with a Special Control specific to this device type. The categories of tests applied to this device are entirely contained within the Special Control. These categories are: Input dynamic range, Input Impedance, Gain Stability, System noise, Multichannel crosstalk, Frequency response, Timing accuracy, and Temporal alignment. For all the categories, we have determined that *Actiwave* performance meets the test criteria in the Special Control. In addition to performance testing, the device has been tested for electrical safety and electromagnetic interference according to internationally recognized standards. The testing according to these standards has raised no issues as to the safety and effectiveness of the present device or the present device compared to the predicate device.

5.6 Conclusion

The results of the tests conducted in accordance with the Special Control demonstrate that the *Actiwave* is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

CamNtech, UK, Ltd.
c/o Mr. Howard Smith
Engineering Director
Upper Pendrill Court, Ermine Street North
Papworth Everard, Cambridge, UK CB233UY

APR 2 9 2010

Re: K100266
Device Name: Actiwave™
Regulation Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph (Without Analysis)
Regulatory Class: Class II (Two)
Product Code: MWJ
Dated: January 25, 2010
Received: January 29, 2010

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K100266

Device Name: Actiwave™

Indications For Use:

The Actiwave Recorder is an ambulatory, body-worn, dermally-affixed, physiological signal and activity recorder. Actiwave is indicated for use in recording physiological waveforms and activity as part of a physiological recording system. The subject is not restricted to a medical environment. The subject may participate in normal activities while the Actiwave recorder is in place. Actiwave is a multi-use recorder. Actiwave may be used wherever quantifiable measurement of human physiological signal waveforms and/or activity are needed. Actiwave may be used in a clinical setting or in basic scientific research under the supervision of a trained clinician.

Prescription Use ____✓____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100266

1 of 1